510(k) summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K013582**

Submitter Information (21 CFR 807.92(a)(1)

Submitter: MAYBE? M.O.M. Inc.
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Summary Date: 5 July 2002

Name of Device and Classification (21 CFR 807.92(a)(2)

Name (Trade): MAYBE? MOM® Mini Ovulation Microscope

Name (Usual): Mini Ovulation Microscope

Classification: 21 CFR 862.1485, Class 1, CEP (75)

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92(a)(3))

The MAYBE? MOM® Mini Ovulation Microscope is substantially equivalent to Clear Plan® Easy Ovulation Test (Unipath Diagnostics Company) cleared under premarket notification K981271.

The MAYBE? MOM® Mini Ovulation Microscope is identical or similar to its predicate in terms of: intended use, risk to user, result interpretation (positive or negative for impending ovulation), test availability (OTC), and clinical performance (ability to identify impending ovulation).

Description of Device (21 CFR 807.92(a)(4)

The MAYBE? MOM® Mini Ovulation Microscope identifies the most fertile day(s) of a woman's menstrual cycle using a direct saliva sample. The fertile day(s) are detected through the observation of distinctive crystallization or ferning patterns seen on a glass slide. The test is self-administered and is completely portable. It requires no reagents nor specific storage conditions and the testing can be performed with relative ease. The results may be interpreted as soon as saliva applied to the slide dries, usually within 2-6 minutes. The MAYBE? MOM® Mini Ovulation Microscope is to be marketed for over-the-counter (OTC) use.

The MAYBE? MOM® Mini Ovulation Microscope consists of:

- a black microscope eyepiece with a microscope slide
- a rubber eye cup
- a plastic cylindrical body
- a battery
- a light source.

All of these parts are in place in the unit. The consumer does not do anything to the Mini Ovulation Microscope except to place a drop of saliva on the microscope eyepiece/slide, press the light source to illuminate the salivary ferning pattern and focus the microscope to obtain the best view.

The Mini Ovulation Microscope is a hand-held, circular shaped mini microscope containing a miniaturized focusing lens and a miniaturized slide. The slide serves as the platform upon which the saliva is placed and for viewing the dried saliva pattern. The device also includes a miniaturized light source (light emitting diode – LED) that serves as the light source and electronic circuitry. The battery is operated with a replaceable 1.5-volt battery. The Mini Ovulation Microscope is completely reusable, and requires only the cleaning of the mini microscope slide to be reused.

The Mini Ovulation Microscope is designed to be used throughout the menstrual cycle. To perform the test, a small drop of saliva is placed on the slide. After the saliva air-dries (usually in 2-6 minutes), the eye piece is brought to close proximity to the eye for viewing. The black button on the bottom of the Mini Ovulation Microscope is pressed to activate the yellow light that allows viewing of the dried saliva pattern. The non-ovulatory (non-fertile) days are identified by "debris-like" substances, such as dots, circles, or random cells. Ovulatory days are characterized by distinct ferning patterns. Days when some ferning and some random "debris-like" patterns are seen are peri-ovulatory days during which some chance of pregnancy exists.

Intended Use (21 CFR 807.92(a)(5))

The MAYBE? MOM® Mini Ovulation Microscope is an over-the-counter device intended to detect the most fertile days of a woman's menstrual cycle by the direct visualization of the characteristic ovulatory fern pattern seen in dried saliva. This fern occurs due to increased levels of ovulatory hormones.

Similarities to the Predicate(s) (21 CFR 807.92(a)(6)

A summary table of the similarities and differences between the Mini Ovulation Microscope and the predicate device (Clear Plan® Easy Ovulation Test) follows.

Comparison of
MAYBE? MOM® Mini Ovulation Microscope
and Clear Plan® Easy Ovulation Test

Parameter	MAYBE? MOM® Mini Ovulation Microscope	Clear Plan® Easy Ovulation Test
Indication For Use	Indication of a woman's fertile and infertile days	Indication of a woman's fertile and infertile days
Use	Reusable	Not reusable
Risk To Consumer	None: non-invasive Results (positive or negative) do not lead to critical decision or outcomes	None: non-invasive Results (positive or negative) do not lead to critical decision or outcomes
Sample Matrix	Saliva	Urine
Measured Effect or Analyte	Salivary fern under the influence of ovulatory hormones	Urinary LH surge under the influence of ovulatory hormones
Result Interpretation	Qualitative: positive or negative for impending ovulation	Qualitative: positive or negative for impending ovulation
Result Stability	Stable Several months [if not longer] as long as dried saliva is not disrupted	Not stable LH stick must be interpreted within minutes of exposing to urine
Test Availability	Over-the-Counter (OTC)	Over-the-Counter (OTC)

Brief Discussion of Nonclinical and Clinical Data (21 CFR 807.92(b)(1.2)
In a consumer use study with 93 pre-menopausal women aged 13 to 53, the MAYBE? MOM® Mini Ovulation Microscope was 97% accurate in identifying the impending ovulation as compared to a urinary LH kit. Salivary fern ing was identified within 48 hours pre or post of the first day of the LH surge in 92/95 cycles.

The readability of the MAYBE? MOM® Mini Ovulation Microscope was validated in 28 untrained woman. The consumers were able to identify salivary fern ing on at least one of the days when a trained reader identified fern ing in 25 of 28 cycles.

Performance Data – Conclusions (21 CFR 807.02(b)(3))
The MAYBE? MOM® Mini Ovulation Microscope is substantially equivalent to the Clear Plan® Easy Ovulation Test. Both methods identify the most fertile days of a woman's menstrual cycle and impending ovulation. Clear Plan® Easy Ovulation Test is a urinary LH kit that identifies the mid-cycle LH surge, and the MAYBE? MOM® Mini Ovulation Microscope detects the characteristic ovulatory fern ing pattern seen in dried saliva. This fern ing occurs due to increased levels of ovulatory hormones.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Maybe?Mom
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JAN 16 2003

Re: K013582/A003
Trade Name: Maybe?MOM® Mini Ovulation Microscope
Classification Regulation Name and Number: Luteinizing hormone test system 862.1485
Regulatory Class: Class I Exempt
Product Code: CEP
Dated: November 12, 2002
Received: November 12, 2002

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

510(k) Number : K 013582

Device Name: Maybe?MOM® Mini Ovulation Microscope

Indications for Use: The Maybe MOM® Mini Ovulation Microscope is intended to be used only to indicate when a woman is ovulating by visualizing a woman's dried saliva on a lens. When a woman is ovulating, the increased secretion of estrogen is associated with a fern-like dried salivary pattern.

Jean Cooper M.S., D.V.M.
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013582

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use ✓
(Per 21 CFR 801.109)